

Docket No. HUI-041DV (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Laurie H. Glimcher et al.

Confirmation No. 3956

Application No. 10/643581

Art Unit: 1633

Filed: August 19, 2003

Examiner: Q.J. Li

For:

METHODS AND COMPOSITIONS RELATING TO MODULATION OF

HEPATOCYTE GROWTH, PLASMA CELL DIFFERENTIATION OR T CELL SUBSET **ACTIVITY BY MODULATION OF XBP-1**

ACTIVITY

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CORRECTED INFORMATION DISCLOSURE STATEMENT (IDS)

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent,

publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 12-0080 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. HUI-041DV.

Dated: January _____, 2007

Respectfully submitted,

MEW/DLN/mch

Elizabeth A. Hanley, Reg. No. 33,505 for Megan E. Williams, Reg. No. 43,270 Registration No. 43,270 LAHIVE & COCKFIELD, LLP One Post Office Square Boston, Massachusetts 02109 (617) 227-7400 (617) 742-4214 (Fax) Attorney/Agent For Applicants

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Sheet 1 4 of

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Application Number	10/643581-Conf. #3956				
Filing Date	August 19, 2003				
First Named Inventor	Laurie H. GLIMCHER				
Art Unit	1633				
Examiner Name	Q.J. Li				
Attorney Docket Number	HUI-041DV				

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		

		FOREI	GN PATENT	DOCUMENTS		
		Foreign Patent Document	Dublication	Name of Patentee or	Pages, Columns, Lines.	
Examiner Initials*			Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T ⁶
	B1	WO-97/39721-A2	10-30-1997	President and Fellows of Harvard College		
	B2	EP-0857780-A1	08-12-1998	Sumitomo Electric Industries, Ltd.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	C1	Andersson, L-O, "Pharmacology of apolipoprotein A-I," Curr. Opin. Lipidol. 8:225-228 (1997)	
	C2	Bancroft, A.J. et al., "Cytokine Production in BALB/c Mice Immunized with Radiation Attenuated Third Stage Larvae of the Filarial Nematode, <i>Brugia pahangi</i> ," <i>J. Immunol</i> . 150(4):1395-1402 (1993)	
	С3	Beg, A.A. et al., "Embryonic lethality and liver degeneration in mice lacking the RelA component of NF-кВ," <i>Nature</i> 376:167-170 (1995)	
	C4	Chen, B.P. et al., "Analysis of ATF3, a transcription factor induced by physiological stresses and modulated by gadd153/Chop10," <i>Mol. Cell Biol.</i> 16:1157-1168 (1996)	
	C5	Chen, C. et al., "In Vitro Induction of T Cell Anergy by Blocking B7 and Early T Cell Costimulatory Molecule ETC-1/B7-2," <i>Immunity</i> 1:147-154 (1994)	
	C6	Chen, H. et al., "Regulation and Activities of α-Fetoprotein," <i>Critical Reviews in Eukaryotic Gene Expression</i> 7(1&2):11-41 (1997)	
	C7	Clauss, I.M. et al., "In Situ Hybridization Studies Suggest a Role for the Basic Region-Leucine Zipper Protein hXBP-1 in Exocrine Gland and Skeletal Development During Mouse Embryogenesis," Dev. Dynamics 197:146-156 (1993)	
	C8	Clerici, M. et al., "A T _H 1→T _H 2 switch is a critical step in the etiology of HIV infection," <i>Immunol. Today</i> 14(3):107-111 (1993)	
	C9	Dallman, M.J., "Cytokines and transplantation: Th1/Th2 regulation of the immune response to solid organ transplants in the adult," Curr. Opin. Immunol. 7:632-638 (1995)	
	C10	Else, K.J. et al., "Cytokine-mediated Regulation of Chronic Intestinal Helminth Infection," <i>J. Exp. Med.</i> 179:347-351 (1994)	
	C11	Fässler, R. et al., "Consequences of lack of ß1 integrin gene expression in mice," Genes & Development 9:1896-1908 (1995)	
	C12	Fauci, A.S., "The Human Immunodeficiency Virus: Infectivity and Mechanisms of Pathogenesis," <i>Science</i> 239:617-623 (1988)	

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				Application Number	10/643581-Conf. #3956	
16	VFORMATION	N DI	SCLOSURE	Filing Date	August 19, 2003	
S	TATEMENT	8Y /	APPLICANT	First Named Inventor	Laurie H. GLIMCHER	
				Art Unit	1633	
	(Use as many sh	eets a	s necessary)	Examiner Name	Q.J. Li	
Sheet	2	of	4	Attorney Docket Number	HUI-041DV	

	C13	Fowler, D.H. et al., "Donor CD4-Enriched Cells of Th2 Cytokine Phenotype Regulate Graft-
		Versus-Host Disease Without Impairing Allogeneic Engraftment in Sublethally Irradiated Mice," Blood 84(10):3540-3549 (1994)
	C14	Fowler, D.H. et al., "Donor Lymphoid Cells of Th2 Cytokine Phenotype Reduce Lethal Graft
		Versus Host Disease and Facilitate Fully Allogeneic Cell Transfers in Sublethally Irradiated
		Mice," Advances in Bone Marrow Purging and Processing: Fourth International Symposium. Prog. Clin. Biol. Res. 389:533-540 (1994)
	C15	Gabay, C. et al., "Acute-Phase Proteins and Other Systemic Responses to Inflammation,"
		New England Journal of Medicine 340(6):448-454 (1999)
	C16	GenBank Accession No. A36299 for transcription factor hXBP-1 – human, dated September 10, 1999
	C17	GenBank Accession No. BAA82600 for hepatocarcinogenesis-related transcription factor
-	C18	(HTF) [Rattus norvegicus], dated April 14, 2000
-	C19	GenBank Accession No. CAA39149 for TREB protein [Homo sapiens], dated March 8, 1993 GenBank Accession No. GI:4827058 for X-box binding protein 1; X-box-binding protein-1
	CIS	[Homo sapiens], dated November 1, 2000
	C20	GenBank Accession No. P17861 for X BOX BINDING PROTEIN-1 (XBP-1) (TREB5
		PROTEIN), April 24, 1993
	C21	Gorczynski, R.M. et al., "Interleukin 12 in Combination With Anti-Interleukin 10 Reverses Graft
<u> </u>	005	Prolongation After Portal Venous Immunization," <i>Transplantation</i> 60(11):1337-1341 (1995)
	C22	Grzych, JM. et al., "Egg Deposition is the Major Stimulus for the Production of Th2 Cytokines in Musica Schiotocomics Manageria (1994) 4202 (1994)
	C22	in Murine Schistosomiasis Mansoni," <i>J. Immunol.</i> 146(4):1322-1327 (1991)
	C23	Gualdi, R. et al., "Hepatic specification of the gut endoderm in vitro: cell signaling and transcription control," <i>Genes Dev.</i> 10:1670-1682 (1996)
	C24	Günes, C. et al., "Embryonic lethality and liver degeneration in mice lacking the metal-
		responsive transcriptional activator MTF-1," EMBO J. 17:2846-2854 (1998)
	C25	Hentsch, B. et al., "Hix homeo box gene is essential for an inductive tissue interaction that
		drives expansion of embryonic liver and gut," Genes Dev. 10:70-79 (1996)
	C26	Hirsch, E. et al., "Impaired migration but not differentiation of haematopoietic stem cells in the
ļ	007	absence of ß ₁ integrins," Nature 380:171-175 (1996)
	C27 C28	Jacks, T. et al., "Effects of an <i>Rb</i> mutation in the mouse," <i>Nature</i> 359:295-300 (1992)
	C20	Khoury, S.J. et al., "Oral Tolerance to Myelin Basic Protein and Natural Recovery from Experimental Autoimmune Encephalomyelitis Are Associated with Downregulation of
		Inflammatory Cytokines and Differential Upregulation of Transforming Growth Factor β ,
		Interleukin 4, and Prostaglandin E Expression in the Brain," <i>J. Exp. Med.</i> 176:1355-1364
i		(1992)
	C29	Kishimoto, T. et al., "Enhanced Expression of a New Class of Liver-enriched b-Zip
		Transcription Factors, Hepatocarcinogenesis-related Transcription Factor, in Hepatocellular
ļ		Carcinomas of Rats and Humans," Cell Growth & Differentiation 9:337-344 (1998)
	C30	Kishimoto, T. et al., "HTF: A B-Zip Transcription Factor That Is Closely Related to the Human
		XBP/TREB5 and Is Activated by Hepatocellular Carcinoma in Rats," <i>Biochem. Biophys. Res.</i>
<u> </u>	C31	Commun. 223:746-751 (1996) Kullberg, M.C. et al. "Infaction With Schietosome manageri Alters Th1/Th2 Cutoking
	USI	Kullberg, M.C. et al., "Infection With Schistosoma mansoni Alters Th1/Th2 Cytokine Responses to a Non-Parasite Antigen," J. Immunol. 148(10):3264-3270 (1992)
	C32	Lee, E. YH. P. et al., "Mice deficient for Rb are nonviable and show defects in neurogenesis
		and haematopoiesis," <i>Nature</i> 359:288-294 (1992)
	C33	Levy, A.E. et al., "Administration of Ingraft Interleukin-4 Prolongs Cardiac Allograft Survival in
		Rats Treated With Donor-specific Transfusion/Cyclosporine," <i>Transplantation</i> 60:405-406
	004	(1995)
	C34	Liou, H-C. et al., "A New Member of the Leucine Zipper Class of Proteins That Binds to the
[]	1	HLA DRα Promoter," Science 247:1581-1584 (1990)
Examiner Signature		Date Considered
Olginature.		Considered

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
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S	TATEMENT B	3Y /	APPLICANT	First Named Inventor	Laurie H. GLIMCHER	
				Art Unit	1633	
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Sheet	3	of	4	Attorney Docket Number	HUI-041DV	

C35	Locksley, R.M. et al., "Helper T-cell subsets in mouse leishmaniasis: induction, expansion and effector function," <i>Immunoparasitology Today</i> 1:A58-A61 (1991)	
C36	Maeda, H. et al., "Adoptive transfer of a Th2-like cell line prolongs MHC class II antigen	
	disparate skin allograft survival in the mouse," International Immunology 6(6):855-862 (1994)	
C37	Maekawa. T. et al., "Mouse ATF-2 null mutants display features of a severe type of meconium aspiration syndrome," <i>J. Biol. Chem.</i> 274(25):17813-17819 (1999)	
C38	Mucenski, M.L. et al., "A Functional c-myb Gene Is Required for Normal Murine Fetal Hepatic Hematopoiesis," <i>Cell</i> 65:677-689 (1991)	
C39	Ono, S.J. et al., "Human X-box-binding protein 1 is required for the transcription of a subset of human class II major histocompatibility genes and forms a heterodimer with c-fos," <i>Proc. Natl. Acad. Sci. USA</i> 88:4309-4312 (1991)	
C40	Paul, W.E. et al., "Lymphocyte Responses and Cytokines," Cell 76:241-251 (1994)	
C41	Pearce, E.J. et al., "Downregulation of Th1 Cytokine Production Accompanies Induction of Th2 Responses by a Parasitic Helminth, <i>Schistosoma mansoni</i> ," <i>J. Exp. Med.</i> 173:159-166 (1991)	
C42	Pearlman, E. et al., "Induction of Murine T-Helper-Cell Responses to the Filarial Nematode Brugia malayi," Infection and Immunity 61(3):1105-1112 (1993)	
C43	Pisa, P. et al., "Selective expression of interleukin 10, interferon γ, and granulocyte-macrophage colony-stimulating factor in ovarian cancer biopsies," <i>Proc. Natl. Acad. Sci. USA</i> 89:7708-7712 (1992)	
C44	Rapoport, M.J. et al., "Interleukin 4 Reverses T Cell Proliferative Unresponsiveness and Prevents the Onset of diabetes in Nonobese Diabetic Mice," <i>J. Exp. Med.</i> 178:87-99 (1993)	
C45	Reimold et al., "Transcription Factor B Cell Lineage-specific Activator Protein Regulates the Gene for Human X-Box Binding Protein 1," <i>J. Exp. Med.</i> 183:393-401 (1996)	
C46	Reimold et al., "Chondrodysplasia and neurological abnormalities in ATF-2-deficient mice," Nature 379:262-265 (1996)	
C47	Reimold, A. et al., "Control of Terminal B Cell Differentiation by Transcription Factor XBP-1," Arthritis & Rheumatism 42(9 Suppl.):S58 (1999)	
C48	Reimold, A.M. et al., "An essential role in liver development for transcription factor XBP-1," Genes & Development 14:152-157 (2000)	
C49	Rudolph, D. et al., "Impaired fetal T cell development and perinatal lethality in mice lacking the cAMP response element binding protein," <i>Proc. Natl. Acad. Sci. USA</i> , 95(8):4481-4486 (1998)	
C50	Schmidt, C. et al., "Scatter factor/hepatocyte growth factor is essential for liver development," Nature 373:699-702 (1995)	
C51	Servillo, G. et al., "Transcription factor CREM coordinates the timing of hepatocyte proliferation in the regenerating liver," Genes Dev. 12(23):3639-3643 (1998)	
C52	Shearer, G.M. et al., "T helper cell immune dysfunction in asymptomatic, HIV-1-seropositive individuals: the role of TH1-TH2 cross-regulation," <i>Chem. Immunol.</i> 54:21-43 (1992)	
C53	Simon, A.K. et al., "Divergent T-cell cytokine patterns in inflammatory arthritis," <i>Proc. Natl. Acad. Sci. USA</i> 91:8562-8566 (1994)	
C54	Takeuchi, T. et al., "Heart Allografts in Murine Systems. The Differential Activation of TH2- Like Effector Cells in Peripheral Tolerance," <i>Transplantation</i> , 53(6):1281-1291 (1992)	
C55	Taub, R., "Transcriptional control of liver regeneration," FASEB J., 10:413-427 (1996)	
C56	Thai, N.L. et al., "Cytokine mRNA Profiles in Mouse Orthotopic Liver Transplantation," Transplantation 59(2):274-281 (1995)	
C57	Tzakis, A.G. et al., "Early Tolerance in Pediatric Liver Allograft Recipients," <i>J. Pediatr. Surg.</i> 29(6):754-756 (1994)	
C58	Uehara, Y. et al., "Placental defect and embryonic lethality in mice lacking hepatocyte growth factor/scatter factor," <i>Nature</i> 373:702-705 (1995)	
	Yamamura, M. et al., "Local Expression of Antiinflammatory Cytokines in Cancer," J. Clin.	

Examiner	Date	
Signature	Considered	

PTO/SB/08a/b (07-05)
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İ	Yoshimura, T. et al., "Multiple cDNA clones encoding nuclear proteins that bind to the <i>tax</i> -dependent enhancer of HTLV-1: all contain a leucine zipper structure and basic amino acid domain," <i>EMBO J.</i> 9(8):2537-2542 (1990)	
	European Search Report for Application No. 05013817.1-2401, dated March 17, 2006	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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